NDA 19-090/S-044
NDA 19-593/S-032

GlaxoSmithKline, Inc.
Attention: Robert J. Bohinski,
Manager Regulatory Affairs
Five Moore Drive
P.O. Box 13358
Research Triangle Park, NC 27709

Dear Mr. Bohinski:

Please refer to your supplemental new drug application dated September 29, 2000, received October 02, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following Zantac® products.

NDA 19-090/S-044 Zantac®(ranitidine hydrochloride) Injection
NDA 19-593/S-032 Zantac®(ranitidine hydrochloride) Injection Premixed

These supplemental new drug applications provide for revisions to the *Geriatrics* subsection of the CLINICAL PHARMACOLOGY section, the *Geriatric Use* subsection of the PRECAUTIONS section, and the *Dosage Adjustment for Patients With Impaired Renal Function* subsection of the DOSAGE AND ADMINISTRATION section of the package insert; to include information on the use of Zantac® in the elderly.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental applications are approved effective on the date of this letter.

The revisions are as follows:

1. The *Geriatric Use* subsection of the PRECAUTIONS section of the PI:

   "This drug is known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, caution ~~care~~ should be exercised ~~taken~~ in dose selection, and it may be useful to monitor renal function (see CLINICAL PHARMACOLOGY: Pharmacokinetics: Geriatric Use and DOSAGE AND ADMINISTRATION: Dosage Adjustment for Patients with Impaired Renal Function)."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted September 29, 2000). These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDAs 19-090/S-044, and 19-593/S-032." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal
and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research